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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,295	02/17/2004	Jeffrey M. Friedman	600-1-087DIV2	7125

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EXAMINER	
SAOUD, CHRISTINE J	
ART UNIT	PAPER NUMBER
1647	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,295	FRIEDMAN ET AL.	
	Examiner	Art Unit	
	Christine J. Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) *1-29 and 41-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-51* ~~are~~ was subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/17/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group V in the reply filed on 29 September 2006 is acknowledged. The traversal is on the ground(s) that the search and examination of the entire application, or at least of Groups VI and V, could be made without serious burden. This is not found persuasive because M.P.E.P. § 803 provides that the separate classification (i.e., class and subclass) of distinct inventions is sufficient to establish a *prima facie* case that the search and examination of the plural inventions would impose a serious burden upon the Examiner. MPEP (808.02) indicates that a serious burden of search can be established by separate classification of the inventions which shows that each invention has attained recognition in the art as a separate subject for inventive effort and also a separate field of search. Such was set forth in the previous Office action for at least groups I-IV and VII-XI and a *prima facie* case of serious burden of search has been established. Furthermore, Applicant has offered no evidence to rebut this showing.

Applicant's arguments with regard to Groups V and VI are persuasive, therefore, the restriction between these two groups is withdrawn and claims 30-40 will be examined together.

The requirement with regard to Groups I-IV and VII-XI is still deemed proper and is therefore made FINAL.

Claims 1-29 and 41-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable

generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 29 September 2006. Claims 30-40 are under examination.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 121 as follows:

It is noted that this application appears to claim subject matter disclosed in prior Application No. 08/292,345, filed August 17, 1994 and Application No. 09/316,393, filed May 11, 2004. A reference to the prior application(s) must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after

compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its

inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Information Disclosure Statement

Applicant's IDS filed 17 February 2004 does not meet the requirements of 37 CFR 1.98. Applicant provided copies of IDS's which were filed in the parent applications. However, Applicant did not correct the IDS information to refer to "the application number of the application in which the information disclosure statement is being submitted (37 CFR 1.98(a)(l)(i)).

For future submissions, the IDS should include the application information for the application in which the IDS is being submitted. Merely copying IDSs submitted in different applications is not proper and can lead to papers which are not matched properly – this results in printer delays. Your cooperation is greatly appreciated.

Applicant's IDS filed 17 February 2004 has been received and considered.

Specification

The abstract of the disclosure is objected to because it is not a "concise" statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art. Correction is required. See MPEP § 608.01(b).

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are directed to methods of measuring the presence of "an ob polypeptide in a sample" using an antibody that binds to the "ob polypeptide". However, there is no recitation of what an "ob polypeptide" encompasses. Antibodies are molecule which bind specific epitopes of proteins, yet, no structure is provided as to what is encompassed by the term "ob polypeptide". The specification does not define "ob polypeptide" such that one of ordinary skill in the art would know that they were in possession of an antibody that bound it. Furthermore, at the time the instant invention was made, "ob polypeptide" was not so defined, that the skilled artisan would know what this term encompassed. The instant specification provides for an "ob polypeptide"

isolated from humans and mice. The claims could be amended to include the structure of these molecules, which may avoid the rejection.

Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a comparison step to a known concentration to evaluate the level of ob polypeptide in a sample.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 37-40 are directed to detecting or diagnosing the presence of a disease associated with elevated or decreased levels of ob polypeptide, however, the instant specification fails to describe the invention claimed. There is no description in the instant specification which correlates any disease or condition with altered levels of ob polypeptide. Claim 37 states "an increase in the level of ob polypeptide as compared to normal levels indicates a disease associated with elevated levels of ob polypeptide" and "decreased level of ob polypeptide as compared to normal levels indicates a disease

associated with decreased levels of ob polypeptide". The instant specification fails to describe any normal levels of ob polypeptide in an individual, and therefore, there is no basis for establishing what would be normal. Without knowing what values are normal or under what conditions ob polypeptide levels increase or decrease, one of ordinary skill in the art cannot make any reasonable determination as to the presence of a disease based solely on an increase or decrease in ob polypeptide levels. Again, there is no disclosure as to any disease or condition which is associated with ob polypeptide levels, and therefore, the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 38-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 38-40 are directed to a method of monitoring a therapeutic treatment of a disease associated with elevated or decreased levels of ob polypeptide in a mammal. However, the claims are not enabled for a method of monitoring a therapeutic treatment because the specification is not enabled for a therapeutic treatment of a disease since no disease has been associated with elevated or decreased levels of ob polypeptide. In order to practice the methods of claims 38-40, there must first be a disease that is

associated with elevated or decreased levels of ob polypeptide. Since there are none disclosed in the instant specification, the claims are not enabled. The specification asserts that AIDS, cachexia, cancer, anorexia nervosa, obesity, type II diabetes, hypertension and elevated blood lipids are diseases which are associated with elevated or decreased levels of ob polypeptide, however, there is no evidence to support this assertion. Without a correlation or nexus between ob polypeptide levels and any one of these conditions, the claims are not enabled.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Weigle et al. U.S. Pat. No. 5,827,734.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud